

## Remarks

### Claim Objections

Claim 95 is objected to because of a typographical error. The word “amylase” has been corrected to “amylose”. Therefore, the objection is obviated and Applicant respectfully requests that the objection be removed.

### Rejection under 35 U.S.C. § 112, first paragraph

Claim 95 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant vigorously disagrees in light of the current amendment.

The Office states that the recitation of “derivatives of starch and cellulose” in claim 95 is not described in the specification in such a way as to reasonably convey to **one skilled in the relevant art** that the inventor, at the time the application was filed, had possession of the claimed invention (emphasis added).

Applicant notes that both modified starches and starch derivatives were known to those skilled in the art at the time of filing the present application. Notably, modified starches and derivatives of starches are so well recognized that they have been assigned codes according to the International Numbering System for Food Additives (INS).

Further, it is well settled in the law that to meet the “written description” requirement all that is required is that a skilled artisan understands that the inventor was in possession of the claimed invention at the time of filing, and even if every nuance of the claims is not explicitly described in the specification, the adequate written description requirement is still met. *Ex parte Parks*, 30 USPQ2d 1234, 1236–37 (B.P.A.I. 1993). The “written description” requirement states that the patentee must describe the invention; **it does not state that every invention must be described in the same way**. Clearly as a field evolves, the balance also evolves between what is known and what is added by each inventive contribution. As stated by the Court in *Falkner v. Inglis*, 79 USPQ2d 1001, (Fed. Cir. 2006), the forced recitation of known material in patent disclosures would only add unnecessary bulk to the specification. Accordingly the *Falkner* Court held that accessible literature sources clearly provided, as of the relevant date, sufficient knowledge regarding the claimed subject matter, such as modified starches and that

satisfaction of the written description requirement was met without the recitation of such subject matter.

Clearly, starches are well known and applicant provided sufficient functional language in claim 95 and the examples in the specification for a skilled artisan to determine an applicable modified starch or a starch derivative. Still further, it is evident that claim 95 expressly recites that applicable starch derivatives or modified starches form complexes with an emulsifier in an alkali solution and in turn form dissolved starch granules as shown in Figure 1. Thus, when using known modified starches or starch derivatives, a skilled artisan, after reading the examples set forth in the application would understand that applicant was in possession of the claimed invention at the time of filing. Applicant requests reconsideration of this rejection under section 112 and the withdrawal of same.

#### **Rejection under 35 U.S.C. § 112, second paragraph**

Claims 87-100 and 103-116 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 87, 100 and 103, thereby obviating this rejection and requests the withdrawal of this rejection.

#### **Claim Rejections under 35 U.S.C. § 102(b)**

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakatsuka et al. (U.S. Patent No. 4,076,846; hereinafter, Nakatsuka). Applicant insists that the Nakatsuka reference does not anticipate the presently claimed invention.

To anticipate a claim or render it obvious, a reference must be enabling. This point was recently reaffirmed in an April 7, 2000 decision of the Court of Appeals for the Federal Circuit (*Helifix Ltd. v. Blok-Lok, Ltd.*, 54 USPQ2d 1299 (Fed. Cir. 2000)). Citing *In re Paulsen*, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994), the court stated that to be anticipating, a prior art reference must:

- 1) disclose each and every limitation of the claimed invention;**
- 2) be enabling; and**
- 3) describe the claimed invention sufficiently to place it in possession of a person of ordinary skill in the field of the invention.**

Nakatsuka does not meet this standard.

Applicant's claimed invention as recited in claim 121 is as follows:

**“A particle comprising alginate and a starch-emulsifier complex.”**

Applicant's particle provides for novel and inventive aspect, that being, a starch-emulsifier formed complex, which is stabilized by the interaction between the starch and the emulsifier. Importantly, the increased hydrophobicity of the emulsifier helps to prevent, or to delay, penetration of water or gastric juices into the matrix once formed into microparticles. Notably, applicant provides a method to prepare such a complex wherein the starch is introduced into alkali solution until the starch granules are completely dissolved and then an emulsifier is added directly to the alkali solution to form a stabilized complex.

In contrast, Nakatsuka described an edible thermoplastic molding compositions that includes a starch material, an inorganic salt of a protein, an organic plasticizer and an edible lubricant. Notably, by reviewing the Nakatsuka disclosure it is very evident that the starch-emulsifier complex of the present invention could not be formed by the preparation of the Nakatsuka compositions. Specifically, Nakatsuka combines the starch and inorganic alkali salt of a protein to form a mixture and then adds an edible hydrophilic plasticizer that is capable of swelling the binary blend of the inorganic salt of a protein and the starch. Finally a lubricant is added to the blend to increase moldability and easy release from the mold. There is no disclosure, teaching or suggestion that a starch-emulsifier complex is or could be formed in the Nakatsuka's blends.

As stated above, a reference is not anticipating unless it discloses each and every limitation of the claimed invention; it is enabling; and it describes the claimed invention sufficiently to place it in possession of a person of ordinary skill in the field of the invention. The Office has not provided any evidence on how a person of ordinary skill in the art would read the cited reference and determine the components and method of synthesis such as that described in applicant's claimed invention without an undue amount of experimentation. *See In re Sheppard*, 144 USPQ 42, (CCPA 1981) (reversing a rejection under 35 U.S.C. Section 102(b) where the asserted prior art reference did not permit someone skilled in the art to possess the claimed invention). Clearly, the cited reference is not enabling and does not put the claimed invention in the hands of one skilled in the art. (*In re Sun*, 31 USPQ2d 1451 (Fed. Cir. 1993)). Clearly, a

starch-emulsifier complex is not formed in the binary blend of Nakatsuka, and when a lubricant is finally introduced the binary blend is already mixed with the hydrophilic plasticizer. Thus, the Nakatsuka reference has not "identically disclosed or described" the presently claimed invention as required of an anticipatory reference applied under section 102. (See *In re Felton*, 179 USPQ 295 (CCPA 1973)).

Accordingly, applicant respectfully submits that claim 121 is patentably distinguishable over Nakatsuka. Withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent NO. 5,362,424; hereinafter, Lee). However the Lee reference suffers from the same shortcomings as that of Nakatsuka, that being, the reference does not in any way describe a particle comprising alginate and a starch-emulsifier complex.

Instead Lee describes an oil/drug emulsion that is then added to an aqueous solution containing a polysaccharide which has metal chelating capacity and emulsifying agents. It is important to recognize that the Lee emulsion is a **two phase system**, that being an oil/aqueous solution mixture that must be subjected to sonication to produce an oil in water emulsion. Notably, there is nothing in this disclosure that discloses, teaches or suggests the starch-emulsifier complex of the present invention. Further, this reference does not even include disclosure for all the limitations of the presently claimed invention.

As such, the Lee reference does not in any way qualify as an anticipatory reference and applicant respectfully requests withdrawal of this rejection.

#### **Claim Rejections under 35 U.S.C. § 103(a)**

Claims 87-96, 98, 103, 104, 108-112, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurzinger (U.S. Patent NO. 6,303,175; hereinafter, Kurzinger) in view of Nakatsuka. Applicant vigorously disagrees and insists that this proposed combination does not disclose, teach or suggest the presently claimed invention.

Kurzinger describes a gel-like fish food that can be used to replace frozen food which in warmer waters degrades too quickly. Kurzinger provides for a feed with high viscosity that stays in the molded form in cool water so that fish have the ability to eat the food having the consistency of a frozen feed. Kurzinger

further provides for components in addition to the gel formers including moisture retainers and components that hold together the feed mixtures such as chelating formers. The process of preparation includes the combination of the animal feed with the gel forming agents to form a highly viscous mixture that retains its form and **does not dissolve** in cold water. Applicant suggests that one skilled in the art reading the Kurzinger reference would have no incentive to go in the direction of applicant's claimed invention which during, as stated in the present specification, the production process removes any gelatinized starches by the addition of an emulsifier to the gelatinized starch. As shown in Figure 1 of the present invention, the gelatinized granule is converted into dissolved granules by the addition of the emulsifier in the alkali solution.

The starch-emulsifier complex of the present invention is created by placing starch in a sodium hydroxide solution at a temperature range of 20 to 65° C until the starch granules are fully absorbed with water and reach equilibrium. The use of a sodium hydroxide solution necessarily means that the gelatinization of the starch occurs at an alkaline pH. An emulsifier is then added to prevent the reannealing of the starch grains upon cooling and neutralization; thus, the creation of a starch-emulsifier complex. Bioactive material is added after the starch-emulsion is adjusted to near neutral pH and an acceptably cool temperature for addition of the bioactive materials.

According to the Office, the combination of Kurzinger and Nakatsuka render obvious the presently claimed invention. Applicant insists that even if the two references are combined, which of course there is no suggestion for such a combination, the proposed combination does not teach and could not possibly provide the particles of the present invention. Just reviewing the production process as described in the two references, it is evident that formation of the presently claimed complexes would be impossible.

As stated above, Kurzinger always adds the gel forming components to the food ingredients and then other ingredients are added with no opportunity or the appropriate conditions for forming a starch-emulsifier complex as in the present invention. Likewise, Nakatsuka combines the starch and inorganic alkali salt of a protein to form a mixture and then adds an edible hydrophilic plasticizer that is capable of swelling the binary blend. Finally a lubricant is added to the blend to increase moldability and easy release from the mold. There is no disclosure, teaching or suggestion that a starch-emulsifier complex is or could be formed in the Nakatsuka's blends or process of production.

Therefore, the combination of Nakatsuka and Kurzinger fails to teach the invention claimed herein, and the Office has failed to present a prima facie case of obviousness for claim 87 in view of Kurzinger and

Nakatsuka. As all of claims 88-96, 98, 103, 104, 108-112 and 114 ultimately depend from claim 87, the rejection is obviated for those claims as well. Therefore, applicant respectfully requests that the rejection under 35 U.S.C. 103(a) in view of Kurzinger and Nakatsuka be removed.

Claims 87, 97-100, 103, 105-107, 113, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112, and 114 above, and further in view of Villamar (WO 02/00035; hereinafter, Villamar). Applicant insists that the addition of Villamar does not rectify the shortcomings of the Kurzinger/Nakatsuka combination.

Villamar is directed to a bioactive food complex product, method for preparing a bioactive food complex product, and method for controlling disease. The bioactive food complex which is manufactured by the stepwise formation of two emulsions. The first emulsion contains a lipid mixed with the bioactive ingredients. The second emulsion is then formed by mixing the first emulsion with polymers. Clearly, Villamar completely fails to teach the starch-emulsifier complex of the present invention. Rather, Villamar teaches a composition wherein polymer is crosslinked with, for example, calcium or potassium, to form a matrix to entrap the lipid-bioactive compound emulsion. See Example 1, on page 20 of Villamar.

Like Kurzinger and Nakatsuka, Villamar does not provide any teaching regarding an animal feed composition comprising a starch-emulsifier complex and like Nakatsuka and Kurzinger, it is not feasible to contemplate that Villamar offers any teaching that would motivate one of skill in the art to go in the direction of applicant's claimed invention.

Thus, the Office has failed to present a *prima facie* case of obviousness for claim 87 and all claims depending therefrom in view of Kurzinger, Nakatsuka, and Villamar. As such, applicant respectfully requests that the rejection under 35 U.S.C. 103(a) in view of Kurzinger, Nakatsuka, and Villamar be withdrawn.

### **Rejoinder of Method Claims**

Applicant requests that when the product claims of the present invention are found patentable, all pending method of making and using claims are examined through the rejoinder procedure in accordance with MPEP §821.04. Rejoinder is proper when an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented

for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

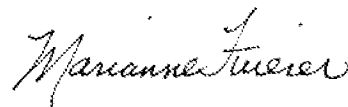
#### **Extension Petition and Fees Payable**

Applicant requests a one month extension extending the April 16, 2009 deadline to May 16, 2009 and the fee for such an extension is being paid herewith by electronic transfer. Further, applicant added one dependent claim and fee for such a new claim is being paid by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

#### **Conclusion**

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Orwig, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Orwig is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,



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